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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

WARNING LETTER
NWE-07-07W

VIA FEDERAL EXPRESS

December 20, 2006

Richard L. Williams, President
Williams Farm Inc.
644 River Road
North Anson, ME 04911

Dear Mr. Williams:

An inspection of your cattle operation located at 644 River Road, North Anson, Maine conducted by a representative of the U.S. Food and Drug Administration (FDA) on October 16 and 23, 2006 confirmed that you offered animals for sale for slaughter as food that were adulterated under section 402(a)(2)(C)(ii) [21 U.S.C. 342 (a)(2)(C)(ii)] and 402(a)(4) [21 U.S.C. 342 (a)(4)] of the Federal Food Drug, and Cosmetic Act (the Act). The inspection also revealed that you caused the new animal drug flunixin to become unsafe under section 512 [21 U.S.C. § 360(b)] of the Act and adulterated within the meaning of section 501(a)(5) [21 U.S.C. § 351(a)(5)] of the Act. You can find the Act and its associated regulations on the Internet through links on the FDA's web page at www.fda.gov.

On or about August 15, 2006, you offered for sale as human food a dairy cow identified with farm tag 1163 and back tag 9138. This cow was transported by a cattle dealer, [redacted]. The cow was sold the same day to [redacted] where it was slaughtered on August 16, 2006. The United States Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) analysis of tissue samples collected from that animal identified the presence of 3.372 parts per million (ppm) of the drug flunixin in the liver tissue of the cow. A tolerance of 0.125 ppm has been established for residues of flunixin in the liver of cattle as codified in Title 21, Code of Federal Regulations, Part 556.286 [21 C.F.R. 556.286].

On or about September 11, 2006, you offered for sale as human food a dairy cow identified by farm tag 13 and back tag 6982. This cow was consigned to [redacted] The cow was delivered to [redacted] where it was slaughtered on September 15, 2006. The USDA/FSIS analysis of tissue samples collected from that animal identified the presence of 19.98 ppm of the drug neomycin in the kidney tissue of the cow. A tolerance of 7.2 ppm has been established for residues of neomycin in the kidney tissue of cattle as codified in Title 21, Code of Federal Regulations, Part 556.430 [21 C.F.R. 556.430]. The presence of these drugs in these tissues above the established tolerance from these animals causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) [21 U.S.C. § 342(a)(2)(C)(ii)] of the Act.

Our investigation also found that you hold animals under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. You lack an adequate system to ensure that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. For example, you failed to maintain complete treatment records. Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) [21 U.S.C. 342 (a)(4)] of the Act.

In addition, you adulterated flunixin within the meaning of Section 501(a)(5) [21 U.S.C. 351 (a)(5)] of the Act when you failed to use the drug in conformance with its approved labeling. "Extra-label use", i.e., the actual or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling, is only permitted if the use is by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship The extra-label use of approved veterinary or human drugs must comply with Sections 512(a)(4) [21 U.S.C. § 360b(a)(4)] and 512(a)(5) [21 U.S.C. § 360b(a)(5)] of the Act and 21 C.F.R. Part 530. Our investigation found that your extra-label use of flunixin failed to comply with these requirements.

For example, your extra-label use of flunixin resulted in an illegal drug residue in violation of 21 C.F.R. 530.11(d). Because your extra-label use of this drug was not in compliance with 21 C.F.R. Part 530, the drug is unsafe under section 512(a) [21 U.S.C. § 360(a)] of the Act, and you caused it to be adulterated within the meaning of Section 501(a)(5) [21 U.S.C. § 351(a)(5)] of the Act.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the food you distribute is in compliance with the law. You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

Additionally, our investigation found you use a medicated milk replacer containing oxytetracycline and neomycin for calves intended to be sold for bob veal. The use of this medicated milk replacer in calves to be sold for veal is contrary to its label. The label of this drug contains the statement, "Do not use in calves to be processed for veal." Because the Act does not permit the extralabel use of medicated feeds, you cannot use this medicated milk replacer in calves you sell for veal.

You should notify this office in writing of the steps you have taken to bring your firm into compliance with the law within 15 working days of receiving this letter. Your response should include each step that has been taken or will be taken to correct these violations and prevent their recurrence. If corrective actions cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Anthony P. Costello, Compliance Officer, 1 Montvale Avenue, Stoneham, MA 02180. If you have any questions about this letter you can contact Mr. Costello at 781 596-7716.

Sincerely,

Gail P. Costello
District Director
New England District Office

cc.

Julie A. Cornett D.V.M.
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